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Dockets Management Branch
Food and Drug Administration
5600 Fishers Lane Room 1061
Rockville, MD 20857

Re: Draft Guidance for Industry; Placing the Therapeutic Equivalence
Code on Prescription Drug Labels and Labeling
Docket No. 98D-1266
64 Fed. Reg. 4434 January 28, 1999

The National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) submits these comments on the *Draft Guidance for Industry for Placing the FDA Therapeutic Equivalence Code on Prescription Drug Labels and Labeling*.

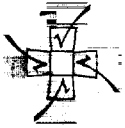
The mission of the National Coordinating Council for Medication Error Reporting and Prevention is to promote the reporting, understanding, and prevention of medication errors. Since its inception in 1995, the Council has examined various aspects of medication error throughout the medication use continuum and issued recommendations for error prevention including recommendations on safer labeling and packaging of drug products. The NCC MERP is a coalition of 16 national organizations and agencies in addition to the Food and Drug Administration. It is the general consensus of the Council as a whole, not the individual delegates or the organizations or agencies that they represent, that is reflected in this document.

The Council disagrees with this proposal, and believes that the Agency needs to consider carefully the implications of adding another piece of information to the manufacturer's label. The Council offers the following:

The guidance applies to all prescription drug product labels, including injectables. Some injectables are packaged in very small containers with little space on the label. In 1994, a joint USP-FDA Subcommittee published recommendations for label simplification (USP Pharmacopeial Forum 1994), some of which have already been implemented through the FDA Modernization Act (FDAMA) of 1997. For example, the legend statements, "Federal law prohibits dispensing without prescription" and the "Warning may be habit forming", were eliminated to reduce unnecessary label clutter. The new Therapeutic Equivalence statement may contradict the purposes of this joint project, (i.e., to assure that nothing detracts from the primary purpose of a drug label; and, to assist the user in proper identification of the product contents) and for this reason, and not just with regard to injectables, the Council disagrees with the proposal.

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The guidance document does not include any requirement for systematic field testing by health care professionals or review by human factors experts (through failure mode and effects analysis), before new labels can be used by the industry. The Council recommends that the Agency require such testing.

Physicians, nurses and patients are unlikely to be familiar with the Therapeutic Equivalence codes. For example, brand manufacturers may indicate that a product is NOT therapeutically equivalent to a specific product. The concern is that a health care practitioner unfamiliar with the codes in the Orange Book may confuse the rating to mean that substituting one product with the other is appropriate.

Because certain health care professionals may be unfamiliar with the therapeutic equivalence codes, they are more likely to translate them to mean something with which they are familiar. Examples include potential for confusion with prescription abbreviations, and medical terms. For example, Bx is also a medical abbreviation meaning "biopsy"; AB has at least seven other meanings among them "antibiotic" (1)

The effect of having multiple drug names on the same container is unknown, as is the impact, if any, on the administration of therapeutic substitution programs approved by institutional formulary committees. The Council recommends against including a second product name on the label.

The proposed system will have important marketing implications for both generic and brand products. Although not the intention of the Guidance document, there is a danger that prescription drug labels will be used as a marketing or counter-marketing tool.

The Council recognizes and agrees with the Agency's desire to assist the health professional in determining whether a specific drug product is therapeutically equivalent to another. However, the Orange Book information is readily available, including on-line on FDA's web site.

The National Coordinating Council for Medication Error Reporting and Prevention appreciates the opportunity to comment on this draft guidance. In the interest of patient safety, it is important that other creative ways to communicate this information are explored, tested, and exhausted before additional information is added to prescription drug labels.

Sincerely,

Diane D. Cousins, R.Ph.

Secretary

National Coordinating Council for Medication Error Reporting and Prevention

(1) Davis, NM. Medical Abbreviations: 12,000 Conveniences at the Expense of Communications and Safety. Eighth Edition.